REMARKS

This application is a broadening reissue application that was filed within two years of the issue date of U.S. Patent No. 6,264,659. Claims 13-24 are now pending. In response to the Restriction Requirement mailed June 9, 2006, the Applicant hereby elects group III (claim 24) without traverse. Claims 1-12 have been canceled without prejudice. Original claims 13-22 have been amended to depend from new independent claim 24. New claims 23 and 24 have been previously added by Supplemental Amendment. New claim 23 has been amended in this paper to now depend from independent claim 24, and as a result "The injection device of..." has been amended to read "The system for treating an intervertebral disk of..." The new claims do not recapture subject matter surrendered during prosecution of U.S. Patent No. 6,264,659.

In the Notice of Non-compliant Amendment mailed July 24, 2006, the Office indicated that the amendments to the claims filed July 17, 2006 were non-compliant because each claim had not been provided with the proper status identifier, and as such, the individual status of each claim could not be determined. The applicant believes that this non-compliance was in reference to an omission of an acceptable indication that claims 1-12 had been canceled. Through this submission, the applicant has corrected this apparent oversight. Furthermore, the Applicant believes that the status identifiers used in connection with amended claims 13-22 (e.g. "amended," "twice amended") are consistent with the requirements for amending the claims in a reissue application as set forth in 37 CFR 1.121(i) and 37 CFR 1.173(b)(2).

Claim Status

Claims 13-24 are now pending. Claims 1-12 have been canceled without prejudice. Claims 13-22 have been amended. New claims 23 and 24 have been added. The status of the pending claims is as follows.

CLAIM	STATUS
1-12	Canceled
13-22	Amended
23-24	New

Explanations For Amendments To Claims

The support in the disclosure of U.S. Patent No. 6,264,659 for the changes made to the claims (*i.e.,* amended claims 13-22 and new claims 23-24) is found in at least the following sections of the '659 patent set forth below under the respective claim(s).

Claim 13 has been amended as follows:

13. (Twice Amended) The [injection device] system for treating an intervertebral disk as defined in claim [4] 24, wherein said [heater] heating element heats said thermoplastic material for flowing at a temperature between about 150C and 200C.

Line No.	Support For Amendment
1-2	Figure 3 (showing a heating element 28 provided to heat the thermoplastic material). Column 4, lines 53-56 (a heater 28 is provided to heat the thermoplastic material).
2-3	Column 5, lines 21-27 (Generally the lowest temperature to which the thermoplastic material is heated while utilizing a large diameter needle such as 1 centimeter in diameter with a relatively high axial force may be 50 C, while the highest temperature will be less than about 250 C. The optimum temperature is about 185 C, within an optimum range between about 150 C and 200 C).

Claim 14 has been amended as follows:

14. (Twice Amended) The [injection device] system for treating an intervertebral disk as defined in claim [4] 24, wherein said thermoplastic material comprises a linear crystalline polymer.

Line No.	Support For Amendment
1-2	Column 2, lines 25-30 (A thermoplastic material which has been found to be highly satisfactory is gutta percha which is normally combined with other elements or ingredients in a suitable gutta percha compound. Gutta percha is a linear crystalline polymer which melts at a predetermined temperature, and a random but distinct change in structure results).

Claim 15 has been amended as follows:

15. (Twice Amended) The [injection device] system for treating an intervertebral disk as defined in claim [4] 24, wherein said thermoplastic material comprises a gutta percha compound in which gutta percha is between 15% and 40% by weight of the compound.

Line No.	Support For Amendment
1-3	Column 2, lines 25-30 (A thermoplastic material which has been found to be highly satisfactory is gutta percha which is normally combined with other elements or ingredients in a suitable gutta percha compound. Gutta perdha is a linear crystalline polymer which melts at a predetermined temperature, and a random but distinct change in structure results. Column 2, lines 45-52 (A suitable gutta percha compound is dental gutta percha which contains by weight only about 20% gutta percha with zinc oxide comprising about 60% to 75% of the material. The remaining 5% to 10% consists of various resins, waxes, and metal sulfates. The percentages listed are directed to an optimum gutta percha compound. The preferred percentage of gutta percha is in the range of 15% to 40%.)

Claim 16 has been amended as follows:

16. (Twice Amended) The [injection device] system for treating an intervertebral disk as defined in claim [4] 24, wherein said injection needle is formed of a ceramic material.

Line No.	Support For Amendment
1-2	Figure 3 (an injection needle 38 preferably formed of silver extends from body 24 and has a ceramic sheath 40 about a portion of needle 38). Column 2, lines 63-66 (The injection device may utilize a silver needle, encased in ceramics, of about 20 to 30 centimeters in length with a diameter as high as 1 centimeter).

Claim 17 has been amended as follows:

17. (Twice Amended) The [injection device] system for treating an intervertebral disk as defined in claim [4] 24, further comprising:

an expandable sleeve about said needle adjacent an extending end of said needle to define an annulus between said needle and said sleeve, so that pressurized fluid communicating with the annulus expands said sleeve outwardly.

Line No.	Support For Amendment
1-3	Figure 7 (a detachable balloon dilator sleeve 106 extends about the extending end of needle 104 having lateral openings 107).
4-5	Figure 7 & Column 6, lines 62-67 (Piston 108 is effective to pressurize the fluid for flow through openings 107 for expansion of sleeve 106 as shown in broken lines in FIG. 7. Dilator sleeve 106 upon injection of needle 104 in a disk of the spine is expanded for exerting an expanding force against the disk).

Claim 18 has been amended as follows:

18. (Amended) The [injection device] system for treating an intervertebral disk as defined in claim 17, wherein said needle has openings thereon for the supply of a pressurized fluid to said annulus for expanding said sleeve.

Line No.	Support For Amendment
1-3	Figure 7 & Column 6, lines 62-67 (a detachable balloon dilator sleeve 106 extends about the extending end of needle 104 having lateral openings 107 Piston 108 is effective to pressurize the fluid for flow through openings 107 for expansion of sleeve 106 as shown in broken lines in FIG. 7. Dilator sleeve 106 upon injection of needle 104 in a disk of the spine is expanded for exerting an expanding force against the disk).

Claim 19 has been amended as follows:

19. (Twice Amended) The [injection device] system for treating an intervertebral disk as defined in claim [4] 24, further comprising:

a piston adjacent an end of said [plug] thermoplastic material for exerting a force against said [plug] thermoplastic material; and

a hand operated trigger [is] operatively connected to said piston and upon actuation [is] effective to force said thermoplastic material from said needle when said thermoplastic material is heated to a flowing state.

Line No.	Support For Amendment
1-3	Figure 3 (injection gun 22 has a body 24 with removable plunger 26 adapted to receive a cylindrical plug of the thermoplastic material 20). Figure 7 (a piston for pressurizing the fluid). Column 4, lines 51-53 (injection gun 22 has a body 24 with a removable plunger 26 adapted to receive a cylindrical plug of the thermoplastic material 20). Column 6, lines 56-59 (a disk dilator assembly generally indicated at 100 having a cylindrical chamber 102 with an inert fluid such as saline therein and a piston 108 for pressurizing the fluid).
4-6	Figure 3 (a hand operated trigger for activating a force). Column 4, lines 59-62 (a hand operated trigger 42 may be activated for forcing thermoplastic material 20 from the end of needle 38 upon heating of the thermoplastic material 20 to a predetermined temperature).

Claim 20 has been amended as follows:

20. (Twice Amended) The [injection device] system for treating an intervertebral disk as defined in claim [4] 24, further comprising[;]:

a hand operated trigger operatively connected to said [plug] thermoplastic material and upon actuation [is] effective to force said thermoplastic material from said needle when said thermoplastic material is heated to a flowing state.

Line No.	Support For Amendment
1-4	Figure 3 (injection gun 22 has a body 24 with a removable plunger 26 adapted to receive a cylindrical plug of the thermoplastic material 20). Figure 3 (a hand operated trigger for activating a force). Column 4, line 51-53 (injection gun 22 has a body 24 with a removable plunger 26 adapted to receive a cylindrical plug of the thermoplastic material 20). Column 4, lines 59-62 (a hand operated trigger 42 may be activated for forcing thermoplastic material 20 from the end of needl e38 upon heating of the thermoplastic material 20 to a predetermined temperature).

Claim 21 has been amended as follows:

21. (Twice Amended) The [injection device] system for treating an intervertebral disk as defined in claim [4] 20, [further comprising;] wherein:

[the] said chamber for receiving [the plug] said thermoplastic material is provided in a plunger removable from an injection device body.

Line No.	Support For Amendment
1-3	Figure 3 & Column 4 lines 48-50 (injection of thermoplastic material 20 within the annulus fibrosus 12 by an injection device or gun illustrated schematically at 22 is shown. Injection gun 22 has a body 24 with a removable plunger 26 adapted to receive a cylindrical plug of the thermoplastic material 20). Column 2, line 66 – Column 3, line 4 (The size of the needle may depend on such factors as the amount of thermoplastic material to be injected, the temperature of the thermoplastic being injected, and the axial pressure applied by the injection device, such as a piston or plunger, to the thermoplastic material to force the heated material from the end of the needle into the spine).

Claim 22 has been amended as follows:

22. (Twice Amended) The [injection device asa] system for treating an intervertebral disk as defined in claim [4] 24, further comprising[;]:

a [heater] heating element control unit having an adjustable temperature control to provide a selected temperature for said [heater] heating element.

Line No.	Support For Amendment
1	Column 2, lines 61-67 (an injection device utilized for heating and injecting the thermoplastic material, the device may utilize a silver needle encased in ceramics).
2-3	Figure 3 and Column 4, lines 53-56 (a heater 28 is provided to heat the thermoplastic material 20 and a heater control unit 30 having an adjustable temperature control knob 32 is provided with a temperature readout at 34).

New claims 23-24 find support as follows:

Claim No.	Support For Addition
23	Column 2, lines 28-29 (gutta percha is a linear crystalline polymer which melts at a predetermined temperature, and a random but distinct change in structure results).
24	Column 2, line 12-17 (the present invention is particularly directed to a process for treating the spine including the injection of a thermoplastic material heated to a predetermined temperature for injection into the nucleus pulposus in a flowing state where it cools and sets at body temperature into a non-flowing state). Column 2, lines 61-63 (an injection device, such as an injection gun, is utilized for heating and injecting the thermoplastic material under a predetermined pressure within the spine). Column 4, line 48 – Column 5, line 27 (description of use of device to heat thermoplastic material and inject into annulus fibrosus to cool to form a resilient cushion).

CONCLUSION

The foregoing amendments have been submitted to place the present application in condition for allowance. Favorable consideration and allowance of the claims in this application is respectfully requested. In the event that there are any questions concerning this Amendment or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

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